PAJUNK
MEDIZINTECHNOLOGIE

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

According to 21 CFR 807.92

JAN 12 2007

Date of Preparation: December 21st, 2006

Submitter Information/ production site:

Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605

Sterilizer:

SteriPro Lab & EO Facility
Dreieichstrasse. 7
64546 Moerfelden
Germany

Contact:

Christian Quass, Regulatory Affairs
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com

US Contact:

Stefan Dayagi
Fon: +01(0)770-493-9305

E-Mail: stefan.dayagi@pajunk-usa.com

Establishment Registration Number:
9611612

Device Information:

Trade Names:	**Pajunks StimuLong Tsui-Method Set**
Common Name:	**Epidural and peripheral stimulation catether set**
Classification Name:	Anesthesia Conduction Kit
Classification Reference:	21 CFR § 868.5140, April 1, 2005,
Poposed Classification:	Regulatory Class II
Proposed Product Classification Code:	CAZ, Kit, Conduction Anesthesia
Panel:	Anesthesiology
Predicate Devices:	1. Pajunks StimuLong Set **K033018, K043130** 2. Pajunks EpiLong Set **K060311**

Item 03

Section 05

Revised 510(k) Summary of Safety and Effectiveness

This section of the submission for **Pajunks StimuLong Tsui Method Set** contains

- The summary of safety and effectiveness
- Submitter Information
- Device Information
- Device Description
- Predicate devices
- Sterilization
- Technology Characteristics
- Safety and Effectiveness: Conclusion

The 510(k) Summary may be copied and submitted to interested parties as required by 21 CFR 807.92.

Device Description

Pajunk GmbH Medizintechnologie is submitting this 510(k) for the **Pajunk StimuLong Tsui Method Set.** The Tsui-Test is a well known technique in epidural anesthesia. It combines the advantages of epidural anestesia and stimulation via catheter in order to verify the area anesthesia is applied to. The Tsui test makes epidural anesthesia much more safe and effective as demonstrated and proven in several studies and articles published since the 1990´s (see section 20 of this submission.

Physicians until now had to combine different devices in order to get a „self-made set acc. Tsui". Dr. Tsui combined Pajunks StimuLong set and technique cleared for peripheral use and Pajunks EpiLong set and technique for epidural use to have a striking safe and effective alternative to „selfmade in-house devices".

The devices for epidural Anesthesia (EpiLong) and peripheral Anesthesia employing stimulation via catheter (StimuLong) are already cleared for market seperately without claiming specific patient populations. **The basis of this submission** is to combine the indications for use of this two cleared device: peripheral and epidural stimulation guided anesthesia.

The components which are part of the subject device kit have already gained market clearance. They are combined under a new indication on customers demands.

The predicate devices are Pajunks own products cleared for a non specified population, i.e. for use with adult patients. In order to demonstrate safety and effectiveness Pajunk provides clinical lieterature from Dr. Tsui as well as a clinical evaluation.

Pajunks StimuLong Tsui Method Set are single use, sterile, non-pyrogenic and latex free medical device kits.

They are intended for continuous peripheral or epidural anesthesia delivery using the Polyamide indwelling catheter. The catheter has to be removed or replaced after 72 hours. An electrical stimulus may be applied via catheter in order to precisely identify the area anesthesia is intended to be applied to.

Predicate Devices

The devices Pajunk claims substantial equivalence with are **Pajunks StimuLong Set and UP cannulas** cleared under **K000722**, **K033018, K043130, K 040965** and **Pajunks EpiLong Set** cleared under **K060311**.

The indications of **StimuLong** and **EpiLong** are already cleared for market.

Because the devices are technical cleared this submission concentrates on the clinical discussion of the combination of advantages of epidural and stimulating peripheral anesthesia.

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission. Because there is no change in technology or material the focus is set on the clinical literature review in section 10 of this submission.

Sterilization

Sterilization method: EtO

The contract sterilizer and the sterilizing process are identical to the ones used for all of Pajunks devices provided sterile, especially the anesthesia conduction devices cleared for the US market in several Premarket Notification submissions.

By annual validation and quarterly verification as well as by shelflife testing the sterilization procedure is claimed to be safe and effective for several years now.

Technology Characteristics:

The **Pajunks StimuLong Tsui Method Set** provides a coated Tuohy cannula, a StimuLong catheter, StimuLong adaptor, valve, adaptor cables, injection hose, filter, LOR-syringe, catheter fixation device, FixoLong and tightning adaptors. The coating on the cannula is laqueur or NanoLine coating, which has been cleared in **K053283**.

The catheter comes with a catheter container, steel stylett and introductory aid for better handling and shape security. The catheter is closed at tip and equipped with three lateral holes, optional with open tip, an integrated spiral (for enhanced stability) and a stylett. There is no change in components compared to the StimuLong and EpiLong set already cleared for market.

All components are available seperately. Within the indications for use and the components cleared for market the StimuLong Tsui method set is customizable.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission demonstrates that the proposed devices are at least as safe and effective as, and substantially equivalent to the predicate devices. A rationale for the method is included in this sumbission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Christian Quass
Regulatory Affairs
Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
Geisingen, Baden-Wurttemberg
Germany 78187

JAN 12 2007

Re: K062900
Trade/Device Name: Pajunks StimuLong Tsui Method Set; Anesthesia Conducting Stimulation Catheter, Epidural and Peripheral; Anesthesia Conducting Epidural Stimulation Catheter; Anesthesia Conducting Peripheral Stimulation Catheter; Stimulation Adapter, Adapter Cable; Injection Valve and Injection Hose; Peripheral Coated Cannulas (NanoLine)
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: CAZ
Dated: December 21, 2006
Received: December 26, 2006

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

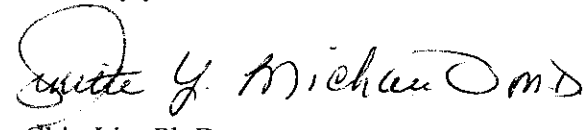
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: **K062900**

Device Name: **Pajunks StimuLong Tsui Method Set**

Indications for Use:

The **Pajunk StimuLong Tsui-Method Sets** are intended for delivery of continuous conduction anesthesia to epidural space as well as optional to peripheral nerves and plexus.

The catheter has to be removed or replaced after 72 hours.

Continuous delivery is accomplished using the conduction catheter. To assist the physician to precisely and safe pinpoint the area of application in peripheral use an electrical stimulus can be applied to the conduction needle.

After placement of the conduction catheter in epidural space or peripheral an electrical stimulus can be applied to its tip via the catheter adapter.

The set is to be used with adults and in pediatrics.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anesthesiology, General Hospital
Control, Dental Devices

K062900

Indications for use

510(k) Number: **K062900**

Device Name: **Anesthesia conducting stimulation Catheter, epidural and peripheral**

Indications for Use:

The Pajunk epidural (optional: peripheral) stimulation catheter is placed in the epidural space (otional: peripheral) to precisely identify the target area and to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain for as long as determined by the professional anesthetist and the instructions for use. It has to be removed or replaced after 72 hours.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible] General Hospital,
Infection Control, [illegible]

510(k) Number K062900

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Indications for use

510(k) Number: **K062900**

Device Name: **Anesthesia conducting epidural stimulation Catheter**

Indications for Use:

The Pajunk epidural stimulation catheter is placed in the epidural space to precisely identify the target area and to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain for as long as determined by the professional anesthetist and the instructions for use. It has to be removed or replaced after 72 hours.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Hospital,
Infection Control, Dental Devices

510(k) Number K062900

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Indications for use

510(k) Number: **K062900**

Device Name: **Anesthesia conducting peripheral stimulation Catheter**

Indications for Use:

The Pajunk peripheral stimulation catheter is placed peripheral to precisely identify the target area and to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain for as long as determined by the professional anesthetist and the instructions for use. It has to be removed or replaced after 72 hours.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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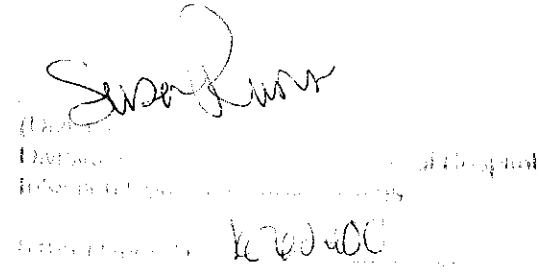
Concurrence of CDRH, Office of Device Evaluation (ODE)



Indications for use

510(k) Number: **K062900**

Device Name: **Stimulation Adapter, Adaptor cable**

Indications for Use:

Pajunks Stimulation Adapter and Adapter cables are accessories to Pajunks sets for epidural and peripheral anesthesia conduction and stimulation, for example StimuLong and StimuLong Tsui-Method.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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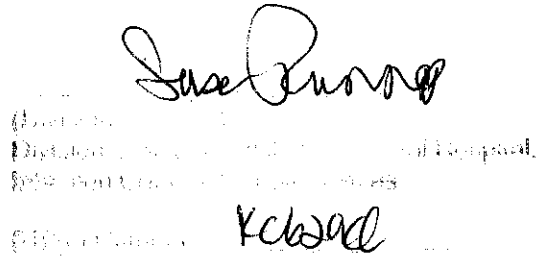

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Indications for use

510(k) Number: **K062900**

Device Name: **Injection valve and injection hose**

Indications for Use:

Pajunks Injection valve and injection hose are accessories to Pajunks sets for epidural and peripheral anesthesia conduction and optional stimulation, for example StimuLong and StimuLong Tsui-Method.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for use

510(k) Number: **K062900**

Device Name: **Peripheral coated Cannulas (NanoLine)**

Indications for Use:

Pajunks peripheral NanoLine-coated cannulas are accessories to Pajunks sets for peripheral anesthesia conduction and stimulation, for example StimuLong and StimuLong Tsui-Method.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K062900